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FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. 5049 A-67209-5/RMS/DCF 09/840,012 04/20/2001 David R. Walt EXAMINER 10/07/2004 ALEXANDER, LYLE Robin M. Silva, Esq. FLEHR HOHBACH TEST ALBRITTON & HERBERT LLP ART UNIT PAPER NUMBER Suite 3400 1743 Four Embarcadero Center

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	- MA
Office Action Summary	09/840,012		
	,	WALT ET AL.	
	Examiner	Art Unit	
The MAILING DATE of this communication and	Lyle A Alexander	1743	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
1) Responsive to communication(s) filed on 20 Ju	<u>ly 2004</u> .		
2a)⊠ This action is <b>FINAL</b> . 2b)☐ This	action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is			
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	3 O.G. 213.	
Disposition of Claims	•		
4) ☐ Claim(s) 11-18 and 32-47 is/are pending in the 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 11-18 and 32-47 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	n from consideration.		
Application Papers			
9) The specification is objected to by the Examiner			
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119			
a) ☐ All b) ☐ Some * c) ☐ None of:  1. ☐ Certified copies of the priority documents 2. ☐ Certified copies of the priority documents 3. ☐ Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list of	have been received. have been received in Application by documents have been received (PCT Rule 17.2(a)).	on No d in this National Sta	ge
Attachment(s)			
Notice of References Cited (PTO-892)	4) Interview Summary (F	PTO-413)	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail Date 5) Notice of Informal Pal 6) Other:		<b>()</b>

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### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-18 and 32-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims (1-16 and 27-30); (22-38 and 57-58) of U.S. Patent No. 6,327,410; 6,023,540 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to compositions of micro spheres/beads immunologically active and label with markers such as fluorescent dyes.

# Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-18 and 32-47 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Walt(USP 4,822,747) or Walt(USP 5,143,853).

The cited art teaches analytical chemistry systems comprising a population of beads encoded with multiple fluorescent dyes.

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## Response to Arguments

Applicant's arguments filed 7/20/04 have been fully considered but they are not persuasive.

Applicants state Walt et al. teaches analytical chemistry systems comprising a population of beads encoded with fluorescent dyes but fails to teach the claimed method. The Office notes Walt et al. teach a method of using a population of fluorescently labeled and encoded beads to detect analytes, which is indistinguishable from the instant claims. Applicants argue with respect to claim 40 the Walt et al. references fail to teach a population of beads having different (e.g. a first and second) optical signatures. The Office maintains the Walt et al. references teach a population of fluorescently labeled /encoded beads which have been read on the claims. Applicants argue the Walt et al. references are silent to separate subpopulation of beads having unique optical signature indicative of chemical functionalities. The Office maintains the references teach beads having associated functionalities that give optical signals in the presence of the analyte of interest. This teaching is indistinguishable from the claimed "optical signature indicative of chemical functionalities". The Office maintains the art teaches a population of beads with subpopulations that give a first signal in the presence of analyte and a second optical signal in the absence of analyte that has been properly read on the instant claims.

#### Conclusion

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nova et al. (USP 5,961,923) and WO 97/12680 [see claim 41 as exemplary] both teach methods of using encoded/labeled beads to detect the analyte of interest.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander Primary Examiner Art Unit 1743

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